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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,916	01/26/2001	Dara W. Frank	650053.91487	6613

7590 06/20/2003

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EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/20/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/770,916

Applicant(s)
Frank et al.

Examiner
Jennifer Graser

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Election, 7/8/02
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 1-14 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group III, claims 15 and 16, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-14 and 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 16 are vague and confusing because the wording of the claim makes it sound as if PcrV is a human protein. The claims should be amended to recite "obtaining a humanized antibody or an isolated human antibody which specifically binds to the *P.aeruginosa* PcrV protein".

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Claims 15 and 16 are also vague and indefinite due to the phrase "or antibody fragment". It is unclear what structure is encompassed by this fragment. Fragments read on as little as one amino acids. There is no functional requirement for the fragment and Applicants have not identified fragments which are immunoprotective. See also 112, enablement rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of treating or preventing *P.aeruginosa* infection through the use of a humanized or human PcrV antibody or antibody fragment. The claims read on preventing *P.aeruginosa* in humans. The specification shows that mice which were passively immunized with rabbit IgG antibodies directed against the full-length recombinant PcrV protein were protected against challenge with the parental wild-type strain of *P.aeruginosa*. However, the specification fails to teach which fragments of a PcrV antibody are needed in order to prevent infection by *P.aeruginosa*. The specification also fails to correlate the effects of the mice/rabbit studies to humans. Pullen et al (Infect.Immun. 66(2): 521-527, 1998) teach that while animals

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immunized with the full-length *Yersinia pestis* V protein (a closely related homolog to the PcrV protein) were protected against challenge with *P.aeruginosa*, peptides from this protein were not found to be protective. Data from their experiments demonstrated that the use of linear V peptides from a region which appeared to be very immunogenic were not protective against even a very small challenge dose (see p.526). Pullen concluded that the protective epitopes were most likely to be conformational. Accordingly, there is a great deal of unpredictability in using antibody fragments to prevent or treat infection caused by *P.aeruginosa*. The instant specification is not enabled for treatment or prevention methods using fragments of a PcrV antibody. As Pullen demonstrates, often it takes more than one epitope to provide protection, and sometimes it takes the full-length protein.

Additional evidences may be provided to support the use of the antibodies to prevent disease in humans, i.e, an acceptable animal model which correlates to humans. Further, additional evidences to support fragments would need to be provided or the claims should be limited to antibodies directed against the full-length protein.

Status of Claims:

6. No claims are allowed. 'A method of treating or preventing *P.aeruginosa* infection in a mammal comprising administering isolated antibodies which specifically bind to the *P.aeruginosa* PcrV protein' is enabled.

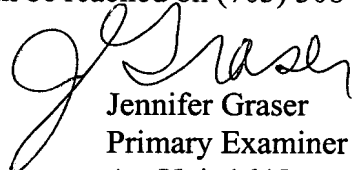
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The prior art teaches that the PcrV protein was known. However, there is no prior art which teaches or suggests 'a method of administering isolated antibodies which specifically bind to the PcrV protein to prevent or treat *P.aeruginosa* infection'.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.


Jennifer Graser
Primary Examiner
Art Unit 1645

6/18/03